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10/659,367	09/11/2003	Fei Chen	60589.000014	3017

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ROBERTS, MLOTKOWSKI & HOBBES
P. O. BOX 10064
MCLEAN, VA 22102-8064

EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Dbeltran@rmhlaw.com
LGallaugher@rmhlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/659,367	CHEN ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-20 and 22-70* is/are pending in the application.

4a) Of the above claim(s) *34-67,69 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-20, 22-33 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed October 24, 2007 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 5, 9-13, 20, 22-25, 28, 30-33 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al (US 6,194,224) in view of Wei et al (US 2003/0119203) or Robinson et al (US 5,726,064).

Good et al disclose a device comprising a sample receiving zone (zone 1)(see Figures 1-3). Good et al disclose the device comprises a reagent zone (second zone) which contains labeled antibodies (non-immobilized molecule) which are specific for the analyte of interest. Good et al disclose the device comprises an area (third zone) that is overlapped by the reagent zone and extends to a test zone. Good et al disclose that this area (third zone) is comprised of a nitrocellulose having a pore size of 200 nm to about 500 nm (col 4). Good et al disclose the device comprises a test zone (fourth zone) having immobilized anlayte (col 3 & col 4). Good et al disclose that the first zone and second zone are overlapping. Good et al disclose that the second zone and third zone are overlapping. Good et al disclose that the different zone can be comprised of different materials. Good et al disclose that the device comprises a liquid sink zone or waste pad (fifth zone) that absorbs excess liquid in the sample. Good et al disclose that the membrane can comprise latex (col 5-6). Good et al disclose that the sample receiving zone comprises a surfactant (ancillary compound) which provides better flow characteristics of the specimen (col 3 and abstract). Good et al disclose that the surfactant works especially well when the sample is a viscous sample.

Good et al differs from the instant invention in failing to teach a calibration zone comprising an immobilized binding agent having an affinity for the labeled non-immobilised molecule.

Wei et al discloses calibration zone in which a binding agent is immobilized and has affinity for a labeled conjugate (for example para. 0012). Wei et al discloses that the device can be a lateral flow device and that the calibration zones can be useful with essentially any membrane based device (page 5). Wei et al discloses that the calibration zone can be used in comparison with the detection zone to calculate the amount of analyte (p. 2 , para 25, p. 3, para. 39). Wei et al discloses that the use of calibration zones provides for improving sensitivity, and reducing errors that otherwise may be introduced by comparing data produced in one assay with data or reference data produced in a different assay (abstract & p. 1).

Robinson et al disclose a device such as a test strip (col 8) having a calibration zone located thereon. Robinson et al disclose that the calibration zone can be located downstream of a measurement zone (see col 33-34, col 9-10). Robinson et al disclose that in competitive assays the calibration zone can have an immobilized reagent which binds to labeled analogue. Robinson et al teaches that this provides for a device which avoids the need for a separate calibration step and provides for the confirmation that various reagents used in the assay procedure are performing according to their specification and to compensate for background interference, temperature and pH changes and other factors originating from the sample matrix which may alter the level of the observed signal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a calibration zone as taught by Wei et al into the device of Good et al because Wei et al teaches that the calibration zones can be useful with essentially any membrane based device and further teaches that the incorporation of calibration zones in lateral flow devices provides for the quantification of analytes, improving sensitivity, and reducing errors that otherwise may be introduced by comparing data produced in one assay with data or reference data produced in a different assay.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a calibration zone as taught by Robinson et al into the device of Good et al because Robinson et al teaches that this provides for a device which avoids the need for a separate calibration step and provides for the confirmation that various reagents used in the assay procedure are performing according to their specification and to compensate for background interference, temperature and pH changes and other factors originating from the sample matrix which may alter the level of the observed signal.

With respect to the recitation "retarding the rate of migration of the sample and the non-immobilised molecule" as recited in the instant claims. Since Good et al disclose the same device and disclose the same pore size in the third zone that applicant uses, the device of Good et al would retard the rate of migration of the sample and the non-immobilised molecule. Thus, Good et al reads on the instantly recited claims.

With respect to claims 12 and 13 as instantly recited. Since Good et al disclose the same structure, materials and pore size as instantly claimed. The porous material of Good et al would bind proteins in the range as recited and would also have a capillary flow-rate as recited.

With respect to the recitation "wherein the amount of the analyte present in the sample is calculated from a signal obtained in the fourth zone and a signal obtained in the calibration zone" as recited. The recitation does not further limit the claims which are directed to a device. The recitation is directed to intended use of the device and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In this case the combination of references teach the same structural limitations as recited in the claims and therefore the combination of references is capable of determining an amount of analyte present in a sample and thus the combination of references read on the claimed invention.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Polzius et al (US 6,130,097) or Schlipfenbacher et al (US 5,160,486).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach the third zone and fourth zone overlapping and the fourth zone and fifth zone overlapping.

Polzius et al teach that it is known in the art to overlap zones on a test strip to provide for fluid contact of the zones (col 4).

Schlipfenbacher et al teach that it is known in the art to overlap zone on a test strip. Schlipfenbacher et al teach that this provides for the zone to be in liquid contact with one another so that they form a liquid transport path along which a liqid flows, driven by capillary forces, from a start zone (col 1 – col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate overlapping as taught by Polzius et al and Schlipfenbacher et al into the third, fourth and fifth zones of Good et al because both Polzius et al and Schlipfenbacher et al show that it is known in the art to overlap zones on a test strip and also show that this provides for fluid contact and a liquid transport path. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating overlapping as taught by Polzius et al and Schlipfenbacher et al into the device of Good et al. Further, it is unclear what applicant intends by claim 6 (see 112 second rejection above). Therefor, the combinations above read on the instantly recited claims.

6. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Davis et al (US 6,352,862).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach a second labeled molecule in the second zone and its binding partner in the forth zone.

Davis et al teach the method and device for determining analytes. Davis et al teach the use of immobilized analytes or anologues and labeled reagents in the strip (col 4, line 64 – col 5, line 3). Davis et al teach the use of several labeled specific binding reagents each carrying a different label in a test strip. Davis et al disclose that this facilitates the manufacture of a multiple analyte testing device (col 4, lines 8-14). Davis et al teaches the use of multiple capture reagents col 8, line 65 – col 9, line 27). Davis et al teach that the determination of more than one analyte can have significant clinical utility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate multiple labeled and multiple immobilized reagents as taught by Davis et al into the modified device of Good et al because Davis et al shows that this facilitates the manufacture of a multiple analyte testing device and also teaches that the determination of more than one analyte can have significant clinical utility. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating multiple reagents as taught by Davis et al into the device of Good et al.

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Lee et al (WO 02/04671).

See above for the teachings of Good et al, Wei et al, and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach a spacer molecule or the spacer molecule is bovine serum albumin (BSA).

Lee et al disclose BSA used as a spacer molecule to immobilize a capture probe to a test strip. Lee et al disclose that the use of this spacer increases the stability of the interaction between the capture probe and the target and thus improves sensitivity of the detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a spacer molecule such as taught by Lee et al into the modified device of Good et al because Lee et al shows that use of this spacer increases the stability of the interaction between the capture probe and the target and thus improves sensitivity of the detection.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al in view of Lee et al and further in view of Henderson et al (US 2004/0072248).

See above for the teachings of Good et al., Wei et al and Lee et al.

Good et at, Wei et al and Lee et al differ from the instant invention in failing to teach the spacer molecule and the analyte being immobilized to the fourth zone are coupled using CMO.

Henderson et al teach the use of carboxymethyloxime (CMO) conjugated to bovine serum albumin and conjugated to an oestrogen and used as a binding substance. Henderson et al disclose that this binding substance is immobilized on the surface of a test strip and used in assays.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate CMO as taught by Henderson et al into the modified

device of Good et al because Henderson shows that it is known in the art to use CMO for immobilization of proteins on the surface of test strips. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating CMO as taught by Henderson et al into the modified device of Good et al.

9. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Frushour et al (US 2003/0059951).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to teach changing the length of the porous material used.

Frushour et al teach that the spatial separation between zones on a test strip and the flow rate characteristics of the porous solid phase material can be selected to allow adequate reaction times during which the necessary specific binding can occur, and to allow the labeled antibody in the labeled antibody zone to dissolve through the porous solid phase material (para. 0055). Therefore, Frushour et al is teaching optimizing the test strip to allow for the desired incubation time.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to change the length of the third zone of Good et al as taught by Frushour et al because Frushour et al teaches that this provides for the optimal reaction times during which the necessary specific binding can occur, and to allow the labeled antibody in the labeled antibody zone to dissolve or disperse in the liquid sample and migrate through the porous solid phase material. Further, the optimal length of the third zone relative to the other zones can be

determined by routine experimentation and thus would have been obvious to one or ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

10. Claims 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al and Wei et al or Robinson et al in view of Sundrehagen (US 6,716,641).

See above for the teachings of Good et al, Wei et al and Robinson et al.

Good et al, Wei et al and Robinson et al differ from the instant invention in failing to specifically state that the ancillary compound decreases non specific binding and provides release of the non-immobilized molecule.

Sundrehagen discloses the use of reagents in zones on a test strip. Sundrehagen disclose that the use of these reagents prevents non-specific binding of the detector reagent and/or analyte (col 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate reagents such as taught by Sundrehagen into the modified device of Good et al because Sundrehagen teaches that this provides for the

prevention of non-specific binding of the detector reagent and/or analyte. Further, it is noted that a review of applicant's specification on pages 25-26 discloses the use of ancillary compounds and what the ancillary compounds provide, but the specification does not disclose a species of the ancillary compound nor provides guidance of what the ancillary compound may be. Therefore, the combination of references teach ancillary compounds the same as applicant has discloses and therefore would be capable of providing the specific characteristics as recited and thus the combination of references read on the claims.

Response to Arguments

11. Applicant's arguments filed October 24, 2007 have been fully considered but they are not persuasive.

Applicant argues that a person of ordinary skill in the field of endeavour of Applicants' claimed invention would find no reason, motivation or suggestion in the aforementioned references to combine the teachings of Good et al. with Wei et al and Robinson et al to achieve the Applicants' claimed device. This is not found persuasive because the references of Robinson et al and Wei et al clearly teach the advantages of the incorporation of a calibration zone into test strips and thus provide the motivation to combine (see 103 rejection for reasons of obviousness). Further, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith,* --USPQ2d--, slip op. at 20, (Bd. Pat. Ap. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Applicant argues that Good et al does not disclose a device for the quantitative determination of an analyte in a sample, wherein the content of the analyte present in the sample is calculated from a signal obtained in the test zone and a signal obtained in the calibration zone and Applicant argues that these functional recitations are directed to intended use of the device and thus, in effect are not considered in determining patentability of Applicants' claims. This is not found persuasive (1) because it appears that applicant is arguing the reference individually and not considering the combination of Good et al with Wei et al or Robinson et al. (2) the combination of references teach the same structures in the same order as currently recited and thus the combination of Good et al with Wei et al or Robinson et al is capable of determining an amount of analyte and as stated in the previous office action, intended use of the device and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

Applicant further argues that the device of Wei et al comprises a calibration zone, which comprises two or more control lines in Wei the amount of analyte may be determined by comparing the intensity level of a detection line 24 generated at the detection zone 31 with the intensity level of the calibration lines to calculate the amount of the analyte present. Applicant states that example 3 indicates that the intensities in the three calibration lines are 0.54 ng, 5.4 ng and 54 ng analyte, respectively. The concentration of analyte of an unknown sample could then be visually determined by comparing the intensity level of the detection line with the intensity level of the three

calibration zones. This is not for persuasive because it appears that applicant is trying to argue that the amended claims only require a single calibration zone and that Wei et al is teaching multiple calibration zones, this is not found persuasive because (1) Wei et al teaches a single calibration zone comprised of control lines (calibration lines) (Fig 1 (32) and p. 1, para. 12, (Thus, Wei differentiates a calibration zone from a calibration line)). Thus, Wei et al is specifically teaching a single calibration zone (same as currently recited) (2) this is not persuasive because the instantly recited claims have open language "comprising" and therefore even though Applicant recites a single calibration zone the currently recited claims do not exclude additional calibration zones. Further, Wei clearly teaches that the calibration zone can be useful with essentially any membrane based device and further teaches that the incorporation of a calibration zone in lateral flow devices provides for quantifying analytes, improving sensitivity and reducing errors. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating a calibration zone as taught by Wei into the device of Good. Further, a person of skill would want to determine the amount of analyte, increase sensitivity and reduce areas in assays and devices.

Applicant argues that the device of Robinson et al includes a number of auxiliary calibration surfaces preferably greater than one and more preferably greater than or equal to four. Applicant also argues that Robinson et al teaches more than one moveable binding molecule. This is not found persuasive because it appears that applicant is trying to argue that the amended claims only require a single calibration zone and that Robinson et al is teaching more than one calibration zone, this is not

found persuasive because the instantly recited claims have open language "comprising" (claim 1, line 2 the device comprising") and therefore even though Applicant recites a single calibration zone the currently recited claims do not exclude additional calibration zones or additional reagents and thus the combination of references read on the instantly recited claims.

Applicant further argues that the construction and function of the Applicants' device is significantly and fundamentally different from that of Good et al., at least because Good et al.'s device lacks the calibration zone and because it does not measure the amount of the analyte but measures only the presence or absence of the analyte. Thus, Good et al's device is a positive/negative test device. The devices of Wei et al and Robinson et al are also significantly distinct and different from Applicants' claimed device for the reasons set forth above. This is not found persuasive because Applicant appears to be arguing the references individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, as stated above the motivation to combine the references is provided and the combined references thus teach the same structural limitations as that recited by applicant and therefore the references are capable of determining the amount of analyte in the sample and further Wei et al specifically teaches that a calibration zone provides for the quantification of analyte, thus, the combined references read on the instantly recited claims.

Applicant argues that the remaining tertiary references combined with the Good et al reference fail to establish a teaching suggestion of motivation provided by the prior art. This is not found persuasive because the reasons for obviousness rejection and the advantages taught by the references were clearly established (see 103 rejections above).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gary W. Counts
Examiner
Art Unit 1641
December 20, 2007

LONG V. LE 12/21/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600